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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,999	06/08/2001	Maxime Ranger	2267.001	1762

21917 7590 09/15/2003

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/15/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,999

Applicant(s)

RANGER ET AL.

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-4,6-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4,6-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

An amendment was received and entered as Paper No. 12 on 6/24/03.

Claims 5 and 10 were canceled and claim 19 was added as requested.

Claims 1-4, 6-9, and 11-19 are pending. Claims 15-18 were withdrawn from consideration in Paper No. 10 as being drawn to a non-elected invention. Applicant timely traversed the restriction requirement in Paper No. 8.

Claims 1-4, 6-9, 11-14, and 19 are under consideration in this Office Action.

Rejections and Objections Overcome

Applicants amendments were sufficient to overcome the objections to grammar and the rejections under 35 USC 112, second paragraph set forth in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-9, 11-14, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-9, 11-14 and 19 are indefinite because it is unclear if the compositions may combine "non-ionic hydrophobic units" only with the "mixtures of ionizable and charged units", or if "non-ionic hydrophobic units" may also be combined with just ionizable or just charged units. Similarly, in part "c." of the claims it is unclear if the compositions may combine "non-ionic hydrophobic units" only with the "mixtures of

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ionizable and charged units", or if "non-ionic hydrophobic units" may also be combined with just ionizable or just charged units.

Claim 19 is also indefinite because requires that a hydrophobic unit must be synthesized from a hydrophobic compound selected from vinyl monomers, vinyl oligomers, or vinyl polymers, and that the hydrophobic compound must be either vinyl-terminated poly(lactide) or vinyl terminated poly(epsilon caprolactone). However, neither vinyl terminated poly(lactide) nor vinyl terminated poly(epsilon caprolactone) is synthesized from vinyl monomers, vinyl oligomers, or vinyl polymers, because these compounds have only one vinyl group, at the terminus. Part "a." of claim 19 was too indefinite to allow a meaningful search.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al (US Patent 5,510,103, issued 4/23/96).

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Yokoyama teaches micelles composed of diblock copolymers comprising hydrophilic blocks and blocks comprising ionizable residues and hydrophobic repeating units. In one embodiment of the invention the hydrophilic block is non-ionizable polyoxyethylene, and the ionic block ionizable moiety is an acetic or propionic acid group (see claim 1, especially line 27 wherein R3 may be propionic acid). Propionic acid comprises a hydrophobic segment (ethylene group) that serves as a non-ionic hydrophobic repeating unit. The propionic acid group can be converted between charged and uncharged states by altering the pH of the medium, or by chemical modification, e.g. covalent addition of an uncharged group (see claim 1, lines 30-35. Claim 14 is included in this rejection because it is a product by process in which the claimed product is disclosed in the cited art, rendering the process by which it was made irrelevant.

Thus Yokoyama anticipates the claims.

Claims 1-9 and 11 stand rejected under 35 U.S.C. 102(e) as being anticipated by Allwohn et al (US Patent 6,372,203, issued 4/16/02).

Allwohn teaches micellar compositions comprising diblock copolymers of hydrophilic saccharide polymers and polymers of charged monomers comprising hydrophobic repeating units. See column 4, lines 56-59; column 5, lines 24-67; column 6, line 43 to column 7, line 8; and column 10, lines 39-46. In one embodiment the charge can be viewed as permanent, i.e. a quaternary amine (see column 5, lines 34-37. In another embodiment, the charge is subject to pH (secondary and tertiary amines, see column 5, lines 34-37). The hydrophobic repeating units required by the claims can be considered to be the vinyl groups, acrylate derivatives, C1 to C12 alkyl groups, or aryl groups (see column 5, lines 37-55). In one embodiment the copolymer comprising

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the charged and hydrophobic entities is a polymer of vinyl esters (see column 6, line 64 to column 7, line 8).

Thus Allwohn anticipates the claims.

Claims 1-4, 12, 13, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kabanov et al (US Patent 6,440,743, issued 8/27/02).

Kabanov teaches micellar compositions comprising diblock, multiblock, and random graft copolymers comprising a hydrophilic, nonionic polymer and a polycationic polymer with hydrophobic repeating units. See entire document, especially the abstract, column 3, line 30 to column 6, line 64; and column 10, lines 4-49. In one embodiment the charge can be viewed as permanent, i.e. a quaternary amine (see column 10, lines 11 and 12. In another embodiment, the charge is subject to pH (secondary and tertiary amines, see column 10, lines 9 and 10). The hydrophobic repeating units required by the claims can be considered to be the ethylene, propylene, butylene, pentylene, or hexylene (see column 10, lines 6-9). The hydrophilic block may comprise acrylamide or acrylamide derivatives.

Response to Arguments

Applicant's arguments filed 6/24/03 have been fully considered but they are not persuasive.

Applicant argues at page 13 of the response that the instant invention distinguishes over Yokoyama because the ionizable and hydrophobic units are distinct, allowing one to vary the ratio of ionic and non-ionic units. This is unpersuasive for two reasons. First, Yokoyama teaches an ionic block ionizable moiety comprising an acetic

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or propionic acid group (see claim 1, especially line 27 wherein R3 may be propionic acid), and Applicant has failed to show that the ethylene unit of propionic acid is not "distinct" from the ionizable unit of propionic acid. Second, the claims do not require that one must be able to vary the ratio of ionic and non-ionic units, so Applicant is arguing limitations that are not in the claims.

Applicant argues at page 15 of the response that Allwohn fails to teach a polyelectrolyte that self assembles to form a supramolecular structure with a hydrophobic core. This is unpersuasive because the claims do not require a structure with a hydrophobic core. As shown at column 10, lines 39-46, the composition of Allwohn can form supramolecular structures such as emulsions and micelles. Because the composition of Allwohn meets the explicit structural limitations of the claims, the function of self assembly is considered to be inherent.

Applicant argues at pages 16 and 17 of the response that Kabanov does not teach or suggest polyelectrolyte self-assemblies that can be obtained without any complexation to oppositely-charged molecules. This is unpersuasive because the claims do not exclude such compositions from their scope. Applicant further argues that Kabanov fails to teach "non-ionic hydrophobic units". This is unpersuasive for the reasons set forth in the rejection. Kabanov teaches non-ionic hydrophobic repeating units such as ethylene, propylene, butylene, pentylene, or hexylene groups (see column 10, lines 6-9).

For these reasons the rejections are maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

This application contains claims **15-18** drawn to an invention nonelected with traverse in Paper No. **8**. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.



DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.

S #	Updt	Database	Query	Time	Comment
S8662	U	USPT	(supramolecular or micell\$) and ((copolymer and (hydrophobic same monomer) and ((charged or ionizable) same monomer))and ((random or multi) same block))	2003-09-10 10:33:25	
S8661	U	USPT	(copolymer and (hydrophobic same monomer) and ((charged or ionizable) same monomer))and ((random or multi) same block)	2003-09-10 10:32:24	
S8660	U	USPT	6201065.pn.and (random block or multi-block)	2003-09-10 10:30:02	
S8659	U	USPT	6201065.pn.and random block or multi-block	2003-09-10 10:29:49	
S8658	U	PGPB	unit and (20030059398)	2003-09-10 09:17:27	
S8657	U	PGPB	20030059398	2003-09-10	

09:17:20

S8656

U

USPT

(caprolactone or polylact\$ or poly lact\$) and ((vinyl or acrylat\$ or acrylamid\$ or alkylacrylat\$ or alkylacrylamid\$ or arylacrylat\$ or arylacrylamid\$) and (copolymer and (hydrophobic same monomer) and ((charged or ionizable) same monomer) and supramolecular))

2003-09-10

09:05:55

S8655

U

USPT

(vinyl or acrylat\$ or acrylamid\$ or alkylacrylat\$ or alkylacrylamid\$ or arylacrylat\$ or arylacrylamid\$) and ((caprolactone or polylact\$ or poly lact\$) and ((vinyl or acrylat\$ or acrylamid\$ or alkylacrylat\$ or alkylacrylamid\$ or arylacrylat\$ or arylacrylamid\$) and (water soluble and (copolymer and (hydrophobic same monomer) and ((charged or ionizable) same monomer) and micell\$))))

2003-09-10

09:05:18

S8654

U

USPT

copolymer and (hydrophobic same monomer) and ((charged or ionizable) same monomer) and supramolecular

2003-09-10

08:58:54

S8653

U

USPT

(caprolactone or polylact\$ or poly lact\$) and ((vinyl or acrylat\$ or acrylamid\$ or alkylacrylat\$ or alkylacrylamid\$ or arylacrylat\$ or arylacrylamid\$) and (water soluble and (copolymer and (hydrophobic same monomer) and ((charged or ionizable) same monomer) and micell\$))))

2003-09-10

08:41:31

S8652

U

USPT

(vinyl or acrylat\$ or acrylamid\$ or alkylacrylat\$ or
alkylacrylamid\$ or arylacrylat\$ or
arylacrylamid\$) and (water soluble and (copolymer and
(hydrophobic same
monomer) and ((charged or ionizable) same monomer) and
micell\$))

2003-09-10

08:39:49

S8651

U

USPT

water soluble and (copolymer and (hydrophobic same
monomer) and ((charged or
ionizable) same monomer) and micell\$)

2003-09-10

08:38:03

S8650

U

USPT

copolymer and (hydrophobic same monomer) and ((charged
or ionizable) same
monomer) and micell\$

2003-09-10

08:37:34

S8649

U

USPT

copolymer and (hydrophobic same monomer) and ((charged
or ionizable) same
monomer) and supramolecular assembly

2003-09-10

08:37:08

S8648

U

USPT

copolymer and (hydrophobic same monomer) and ((charged
or ionizable) same
monomer)

2003-09-10

08:35:35

S8647

U

USPT,PGPB,JPAB,EPAB,DWPI,TDBD
copolymer and (hydrophobic same monomer) and ((charged
or ionizable) same
monomer)

2003-09-10
08:21:09

S8646

U

USPT,PGPB,JPAB,EPAB,DWPI,TDBD
(copolymer and (hydrophobic same monomer) and ((charged
or ionizable) same
monomer))

2003-09-10
08:21:03

S8645

U

JPAB,EPAB,DWPI,TDBD
copolymer and (hydrophobic same monomer) and ((charged
or ionizable) same
monomer)

2003-09-10
08:20:51

S8644

U

JPAB,EPAB,DWPI,TDBD
supramolecular assembly same emulsion

2003-09-10
08:00:30

S8643

U

USPT,PGPB
supramolecular assembly same emulsion

2003-09-10
07:59:22

S8642

U

USPT
6372203.pn. and micell\$

2003-09-10
07:58:17

(FILE 'HOME' ENTERED AT 08:03:00 ON 10 SEP 2003)

FILE 'MEDLINE' ENTERED AT 08:03:06 ON 10 SEP 2003

L1 2 S SUPRAMOLECULAR ASSEMBLY AND EMULSION

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COST IN U.S. DOLLARS

SINCE FILE TOTAL

ENTRY SESSION

FULL ESTIMATED COST

4.98 5.19